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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/828,548	04/19/2004	Dale B. Schenk	15270J-004747US	3885

20350 7590 09/29/2005

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EXAMINER	
KOLKER, DANIEL E	
ART UNIT	**PAPER NUMBER**
1649	

DATE MAILED: 09/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/828,548	SCHENK, DALE B.	
	Examiner	Art Unit	
	Daniel Kolker	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 August 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *56-195* is/are pending in the application.

4a) Of the above claim(s) *74-84,86,101-138 and 185-195* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *59-195* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's remarks and amendments filed 4 August 2005 have been entered.

Election/Restrictions

2. Applicant's election of Group I and the species "late or early onset Alzheimer's disease" in the reply filed on 4 August 2005 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Applicant indicated on the reply filed 4 August 2005 that claims 56 – 73, 85, 87 – 100, 120 – 122 and 139 – 184 read on the elected species or are generic.

In the restriction requirement mailed 4 February 2005, the examiner indicated that claims 120 – 122 are included in group I. Upon further consideration, the examiner believes such inclusion was in error. Claims 120 – 122 are claims drawn to products (pharmaceutical compositions) and should have been included in group II, drawn to antibodies and compositions. Group II includes claims 101 – 119 and 123 – 138. Because claims 120 – 122 depend from claim 64, which is part of group I, they were inadvertently included in this group even though they clearly belong in group II.

3. Applicant's response filed 4 August 2005 was fully responsive to the restriction requirement. However, upon further consideration, the examiner has determined that elected Group I still contains multiple patentably distinct inventions. Thus further restriction is required prior to prosecution on the merits

4. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 56 – 59 (each in part), 60 – 61, 66, 67 – 73 (each in part), 85 (in part), 87 – 90 (in part) 91 – 92, 97, 98 – 100 (each in part), 139 – 152, 153 – 159 (each in part), drawn to methods of treating diseases by administering antibodies which bind to the N-terminus of beta amyloid, classified in class 424, subclass 139.1, for example.

II. Claims 56 – 59 (each in part), 62 – 65, 67 – 73 (each in part), 85 (in part), 87- 90 (each in part) 93 – 96, 98 – 100 (each in part), 153 – 159 (each in part), 160 - 173, drawn to methods of treating diseases by administering antibodies which bind to the C-terminus of beta amyloid, classified in class 424, subclass 139.1, for example.

III. Claims 174 - 176, drawn to methods of sequestering amyloid beta from its bound circulating form in the blood, classified in class 424, subclass 139.1, for example.

IV. Claims 177 - 184, drawn to methods of treating patients comprising administering immunoglobulin peptides, classified in class 424, subclass 130.1, for example.

5. The inventions are distinct, each from the other because of the following reasons:

6. Inventions I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to methods which require starting materials that cannot be substituted for each other. Group I requires administration of antibodies which bind to the N-terminus of A-beta, whereas group II requires administration of antibodies which bind to the C-terminus. Furthermore searches required for consideration of the different methods are not coextensive. Thus consideration of both groups together would present a serious burden for the examiner.

Inventions I and II are not related to either of Invention III or IV. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to different methods with different goals, effects, and starting materials. Groups I and II are drawn to administration of antibodies, whereas group IV is drawn to a broader genus, administration of immunoglobulin peptides. Similarly Group III is drawn to a broader genus, administration of agents having a binding affinity for A beta and additionally the effect, sequestration of A beta in the blood, is not required for Group I or II. Thus the methods are patentably distinct. Furthermore the searches required for Groups I and II are not coextensive with the searches required for either group III or IV, so consideration of either Group III or IV along with Group I or II would be burdensome for the examiner.

Inventions III and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to different methods which require different starting materials and have different effects. Group III requires agents having binding affinity for A beta, whereas Group IV requires immunoglobulin polypeptides. Furthermore Group III requires sequestering of A beta in the blood, which is not required for Group IV. Because the searches required for the groups are not coextensive, there would be a serious burden for the examiner if the two groups were to be considered together.

7. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter and because they require divergent searches, restriction for examination purposes as indicated is proper.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel Kolker whose telephone number is (571) 272-3181. The examiner can normally be reached on Mon - Fri 8:30AM - 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on (571) 272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Daniel E. Kolker, Ph.D.
September 26, 2005

SHARON TURNER, PH.D.
PRIMARY EXAMINER
9-28-05